4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 189 and 700

[Docket No. FDA-2004-N-0188] (formerly 2004N-0081)

RIN 0910-AF47

Use of Materials Derived From Cattle in Human Food and Cosmetics; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or "we") is reopening the comment period for the interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics" that published in the Federal Register of July 14, 2004 (69 FR 42256). The interim final rule prohibited the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. In the Federal Register of September 7, 2005 (70 FR 53063), we amended the interim final rule to make changes, including providing that the small intestine of cattle, formerly prohibited cattle material, could be used in human food and cosmetics if the distal ileum was removed by a specified procedure or one that the establishment could demonstrate is equally effective in ensuring complete removal of the distal ileum. Since 2005, peer-reviewed studies have been published showing the presence of infectivity in the proximal ileum, jejunum, ileocecal junction, and colon of cattle with BSE. Therefore, we are reopening the comment

period for the interim final rule to give interested parties an opportunity to comment on the new studies concerning infectivity in parts of the small intestine other than the distal ileum.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 14, 2004 (69 FR 42256), FDA published an interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics." The interim final rule prohibited the use of certain cattle material to address the potential risk of BSE in human food and cosmetics. The interim final rule designated the small intestine as prohibited cattle material and prohibited its use in human food or cosmetics. In the Federal Register of September 7, 2005 (70 FR 53063), we amended the interim final rule to allow the use of the small intestine if the distal ileum is removed by a procedure that removes at least 80 inches of

uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

On January 12, 2004, the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), issued an interim final rule to designate materials that could potentially contain BSE infectivity as specified risk materials (SRMs) and prohibit their use for human food (see "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle;" 69 FR 1862; January 12, 2004). FSIS's interim final rule designated the distal ileum as an SRM but required that the entire small intestine be removed and disposed of as inedible to ensure the effective removal of the distal ileum. On September 7, 2005, FSIS, like FDA, amended its interim final rule to permit the use of the entire small intestine for human food if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

When the FDA and FSIS amendments to the interim final rules were published in 2005, BSE infectivity had been demonstrated in lymphoid tissue of the distal ileum. In naturally occurring cases, sparse immunostaining had also been observed in the myenteric plexus of the distal ileum indicating the presence of PrP^{Sc}, a TSE-specific protein (Ref. 1). Because the myenteric plexus extends throughout the small intestine, both FDA and FSIS considered that it was possible that infectivity might also exist in the myenteric plexus of the jejunum or the duodenum. We stated in our 2005 amendment to our interim final rule that if we became aware of data indicating that other portions of the small intestine harbored BSE infectivity, we would

take action appropriate to the public health risk. FSIS stated in its 2005 amendment to its interim final rule that while it believed that the primary tissues of concern for spreading the BSE agent had been identified, FSIS would use the results of future studies on BSE to further refine its policies with regard to BSE (70 FR 53043 at 53047; September 7, 2005). In 2007, FSIS issued a final rule to make permanent the interim measures implemented in 2004 and amended in 2005 (72 FR 38700; July 13, 2007).

Since we amended our interim final rule in 2005 and FSIS issued its final rule in 2007, peer-reviewed studies have been published showing the presence of some infectivity in the proximal ileum, jejunum, ileocecal junction, and colon of cattle with BSE. The new scientific data confirms the presence of limited amounts of BSE infectivity in the small intestine outside of the distal ileum of classical BSE infected cattle under experimental inoculation and field conditions. The infectivity levels reported in these studies were much lower than the infectivity levels that were previously demonstrated in the distal ileum.

We have added several peer-reviewed studies (Refs. 2 to 6) to the administrative record. We invite comment on those studies.

Additionally, the European Food Safety authority (EFSA) Panel on Biological Hazards (BIOHAZ) has reviewed and evaluated new data as it relates to the BSE epidemiological situation in the European Union. We have added the EFSA documents to the administrative record as well (Refs. 7 and 8). We have evaluated the data from the studies. Only trace amounts of infectivity have been found in the proximal ileum, jejunum, ileocecal junction, and colon of cattle with naturally occurring cases of BSE. We tentatively conclude that the effect of these traces of infectivity on the risk of human or ruminant exposure to BSE in the United States is negligible. The very low levels of infectivity in parts of the intestine other than the distal ileum,

the sharp decline in the prevalence of BSE worldwide, FDA's BSE-related restrictions on the contents of animal food and feed (see 21 CFR 589.2000 and 589.2001), and the extremely low prevalence of BSE within cattle in the United States due to the presence of effective mitigations and compliance with international standards suggest that the risk from parts of the intestine other than the distal ileum is extremely low. We also note that the World Organization for Animal Health (formerly known as the Office International des Epizooties or "OIE") has not changed its definition of SRMs to include any part of the small intestine in addition to the distal ileum. Based on this assessment, we tentatively conclude that requiring the removal of additional parts of the small intestine would not provide a measurable risk reduction compared to that already being achieved by removal of the distal ileum in all cattle and that it would be appropriate to finalize our interim final rule without changing any provisions related to the small intestine. We invite comment on this tentative conclusion.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.

1. Terry, L.A., S. March, S.J. Ryder, et al., "Detection of Disease Specific PrP in the Distal Ileum of Cattle Exposed Orally to the Agent of Bovine Spongiform Encephalopathy," Veterinary Record, vol. 152, pp. 387-392, 2003.

2. Balkema-Buschmann, A., C. Fast, M. Kaatz, et al., "Pathogenesis of Classical and Atypical BSE in Cattle." Preventive Veterinary Medicine, vol. 102, pp. 112-117, 2011.

3. Hoffmann, C., M. Eiden, M. Kaatz, et al., "BSE Infectivity in Jejunum, Ileum and Ileocaecal Junction of Incubating Cattle," Veterinary Research, vol. 42, p. 21, 2011.

4. Kimura K. and M. Haritani, "Distribution of Accumulated Prion Protein in a Cow With Bovine Spongiform Encephalopathy," The Veterinary Record, vol. 162, pp. 822-825, 2008.

5. Okada H., Y. Iwamaru, M. Imamura, et al. "Detection of Disease-Associated Prion Protein in the Posterior Portion of the Small Intestine Involving the Continuous Peyer's Patch in Cattle Orally Infected With Bovine Spongiform Encephalopathy Agent," Transboundary and Emerging Diseases, vol. 58(4), pp. 333-343, Aug. 2011.

6. Stack M., S.J. Moore, A. Vidal-Diez, et al. "Experimental Bovine Spongiform Encephalopathy: Detection of PrP(SC) in the Small Intestine Relative to Exposure Dose and Age," Journal of Comparative Pathology, vol. 145, pp. 289-301. 2011.

7. "European Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ)," EFSA Journal, vol. 1317, pp. 1-9, 2009.

8. "European Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ)," EFSA Journal, vol. 9(3), p. 2104, 2011.

Dated: February 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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